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MAR 11 2002

510(k) SUMMARY

Device: Oxford Modular Shoulder Prosthesis

Date: 07/17/01

Applicant's name: Corin USA
10500 University Center Drive, Suite 190
Tampa, FL 33612

Phone: (813) 977-4469
Fax: (813) 979-0042

Contact person: Joel Batts, Regulatory Affairs Manager

Classification name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (87HSD)

Shoulder joint metal/polymer semi-constrained cemented prosthesis (87KWS)

C.F.R. section: 21.888.3660, 21.888.3690

Device class: II

Classification panel: Orthopedic

Indications for use

The Oxford Modular Shoulder Prosthesis is indicated for the relief of pain and restoration of function in non-inflammatory degenerative joint disease, including:

- osteoarthritis
- rheumatoid arthritis
- revision cases where other devices or treatments have failed
- correction of functional deformity

- treatment of acute fracture of the humeral head unmanageable using other treatment methods
- cuff tear arthroplasty

Hemi-resurfacing is also indicated for:

- humeral head fractures
- avascular necrosis of the femoral head

Device description

The Oxford Modular Shoulder is a modular total shoulder replacement comprised of 3 components: humeral stem, modular head and glenoid.

The humeral stem and head are made from cobalt-chrome alloy; the glenoid component is made from ultra high molecular weight polyethylene (UHMWPE). The humeral stem has a proximal one-third plasma sprayed coating to provide fixation and a proximal fin with holes to allow for reconstruction of fractures.

Substantial equivalence basis

Based on the following SE table, which compares the Oxford Modular Shoulder to the Biomet Bio-Modular Shoulder (K992119), and the risk analysis, the former is believed to be substantially equivalent.

Features	**Oxford Modular Shoulder**	**Biomet Bio-Modular Shoulder System (K992119)**
Humeral stem substrate	CoCr	Ti6Al4V
Indications for use, in the submission, apply	Yes	Yes
Proximal plasma sprayed titanium coating on humeral stem	Yes	Yes
Lateral fin and finholes on humeral stem	Yes	Yes
Collar on humeral stem	No	Yes
Humeral stem lengths	120mm and 200mm	115mm and 190mm
CoCr modular heads	Yes	Yes
Keeled all-UHMWPE glenoid component	Yes	Yes
Glenoid component sizes	2 sizes, 1 thickness	3 sizes, 2 thicknesses

The guidance document entitled, "Guidance Document For Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement" was consulted during the compilation of this submission. Testing that has been performed accordingly includes:

- static shear testing of the plasma sprayed surface coating
- static tensile testing of the plasma sprayed surface coating
- microstructure and metallurgy analysis of surface coating

On the basis of the above SE table and the test results provided, this device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2002

Mr. Joel Batts
Regulatory Affairs Manager
Corin USA
10500 University Center Drive, Suite 190
Tampa, Florida 33612

Re: K012377
Trade/Device Name: Oxford Modular Shoulder Prosthesis
Regulation Number: 21 CFR §888.3660; §888.3690
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis; Shoulder joint humeral (hemi-shoulder) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWS; HSD
Dated: December 7, 2001
Received: December 11, 2001

Dear Mr. Batts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

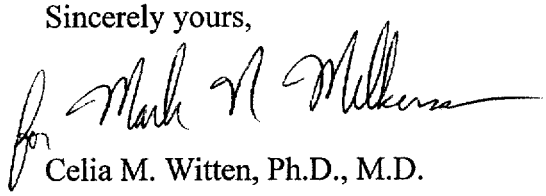
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

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(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012377